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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,474	04/07/2004	Preeti Lal	039386-1568	7560
22428	7590	12/05/2006	EXAMINER	
FOLEY AND LARDNER LLP			LANDSMAN, ROBERT S	
SUITE 500			ART UNIT	
3000 K STREET NW			PAPER NUMBER	
WASHINGTON, DC 20007			1647	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,474

Applicant(s)

LAL ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Election/Restriction

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 17, 18, drawn to a protein and a composition comprising protein, classified in class 530, subclass 350.
- II. Claims 3-7, 9, 10, 12, 13, drawn to a polynucleotide encoding SEQ ID NO:1, vectors, host cells and methods of making protein, classified in class 435, subclass 69.1.
- III. Claim 8, drawn to a transgenic animal, classified in class 800, subclass 8.
- IV. Claim 11, 31, 32, 34, 37, 38, 40-43, drawn to an antibody, classified in class 530, subclass 387.1
- V. Claim 14-16, drawn to a method of detecting a polynucleotide, classified in class 435, subclass 6.
- VI. Claim 19, drawn to a method of treating a disease by administering a protein, classified in class 514, subclass 2.
- VII. Claims 20, 23, 26, 27, drawn to a method of screening ligands, classified in class 435, subclass 7.1.
- VIII. Claims 21, 24 drawn to a composition comprising an agonist, class and subclass undeterminable.
- IX. Claim 22, 25, drawn to a method of treating a disease by administering an agonist or antagonist, class and subclass undeterminable.
- X. Claim 28, drawn to a method of screening of modulators of nucleic acid expression, classified in class 435, subclass 6.
- XI. Claim 29, drawn to a method of screening for toxicity of compounds using nucleic acid expression, classified in class 435, subclass 6.
- XII. Claim 30, 33, 35, 44 drawn to a method of diagnosing a condition using an antibody, classified in class 435, subclass 7.2.
- XIII. Claims 36, 39, drawn to a method of making antibodies, classified in class 435, subclass 70.1.
- XIV. Claim 45, drawn to a method of purifying protein with antibody, classified in class 530, subclass 412 .
- XV. Claims 46, 48-55, drawn to an array, classified in class 536, subclass 23.1.

XVI. Claim 47, drawn to a method of generating an expression profile, classified in class 345, subclass 524 .

B. The inventions are distinct, each from each other because of the following reasons:

Inventions I, II, III, IV, VIII, XV are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polypeptide of **Group I** and the polynucleotide of **Group II** are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide.

Furthermore, searching the inventions of **Groups I and II** together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of **Groups I and II** have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. As such, it would be burdensome to search the inventions of **Groups I and II**.

The polypeptide of **Group I** and the antibody of **Group IV** are patentably distinct for the following reasons: while the inventions of both **Groups I and IV** are polypeptides, in this instance, the polypeptide of **Group I** is a single chain molecule that functions as a **receptor**, whereas the polypeptide of **Group IV** encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of **Group I** and the antibody of **Group IV** are structurally distinct molecules; any relationship between a polypeptide of **Group I** and an antibody of **Group IV** is dependent upon the correlation between the

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scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptide of **Group I** is a large molecule which contains potentially hundreds of regions to which an antibody must bind, whereas the antibody of **Group IV** is defined in terms of its binding specificity to a small structure within **the disclosed SEQ ID NO.** Thus, immunization with the polypeptide of **Group I** would result in the production of antibodies outside the scope of **Group IV.** Therefore, the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of **Group I** and **Group IV** would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody which to the polypeptide require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of **Group IV.** Furthermore, antibodies which bind to an epitope of a polypeptide of **Group I** may be known even if a polypeptide of **Group I** is novel. In addition, the technical literature search for the polypeptide of **Group I** and the antibody of **Group IV** is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

The polynucleotide of **Group II** and the antibody of **Group IV** are patentably distinct for the following reasons: the antibody of **Group IV** includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of **Group IV** which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of **Group II** will not encode an antibody of **Group IV**, and an antibody of **Group IV** cannot be encoded by a polynucleotide of **Group II.** Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of **Groups IV** and **II** would impose a serious search burden since a search of the polynucleotide of **Group II** would not be used to determine the patentability of an antibody of **Group IV** and vice-versa.

The transgenic animals of **Group III** are distinct from polynucleotide, polypeptides, antibodies and arrays. Animals are organisms. No other **Group** is.

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The array of Group XV is independent from Groups I, II and IV. Arrays use polynucleotides, which are distinct from polypeptides as discussed above. Arrays are also distinct from organic and inorganic compounds. Furthermore, arrays would comprise more than just the polynucleotide of Group II. To search arrays comprising numerous polynucleotides would be an undue burden.

Inventions I and VI, VII, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Invention I is unrelated to Inventions V, IX, XII, XIV, XVI because the product of Group I is not used or otherwise involved in the processes of Groups V, IX, XII, XIV, XVI.

Invention II is unrelated to Inventions IV-VII, IX, XII-XIV because the product of Group II is not used or otherwise involved in the processes of Groups IV-VII, IX, XII-XIV.

Inventions II and X, XI, XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Invention III is unrelated to Inventions V-VII, IX-XIV, XVI because the product of Group III is not used or otherwise involved in the processes of Groups V-VII, IX-XIV, XVI.

Invention IV is unrelated to Inventions V-VII, IX-XI, XIII, XVI because the product of Group IV is not used or otherwise involved in the processes of Groups V-VII, IX-XI, XIII, XVI.

Inventions IV and XII, XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Invention XV is unrelated to Inventions V-VII, IX-XIV because the product of Group XV is not used or otherwise involved in the processes of Groups V-VII, IX-XIV.

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Inventions XV and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The array can be used for drug screening.

Inventions V-VII, IX-XIV, XVI are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Furthermore, in order to be fully responsive, in addition to electing a Group, Applicants must further elect one SEQ ID NO from 1-134 or SEQ ID NO:135-268 depending on the Group elected.

C. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17 (h).

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern); alt F 10 AM – 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER